K050758

DEC 2 2 2005

510(k) SUMMARY
Chempaq A/S's Chempaq XBC Analyzer

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Chempaq A/S
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Date Prepared: 31 August 2005

Name of Device and Name/Address of Sponsor

Chempaq XBC Analyzer
Chempaq A/S
Symbion Science Park, Fruebjergvej 3, DK-2100
Copenhagen, Denmark

Common or Usual Name

Automated Differential Cell Counter

Classification Name

Automated Differential Cell Counter

Predicate Device

Coulter® A^{C}T™ diff Analyzer, manufactured by Beckman Coulter, Inc.

Intended Use / Indications for Use

The Chempaq XBC Analyzer is an in vitro diagnostic method intended for the quantitative determination of the concentration of white blood cells

("WBC"); granulocytes ("GRN"); lymphocytes ("LYM"); monocytes ("MON"); and total hemoglobin ("Hb") in whole-blood samples (finger stick or venous sample).

The Chempaq XBC Analyzer is indicated for use in: clinical laboratories, and for point-of-care hematology determinations in doctors' offices or by healthcare professionals in hospital settings to identify and classify one or more of the formed elements of blood.

Technological Characteristics

The Chempaq XBC Analyzer consists of a single use cartridge, called the PAQ (Particle Analyzer and Quantifier), and a stationary Reader with a docking station, called a Cradle. The PAQ is connected to the Cradle by a simple push fit. The PAQ includes all required reagents and will, when connected to the Cradle, perform all sample manipulations required for the analysis. The sample manipulation is facilitated by electrical and pneumatic connections between the PAQ and the Cradle. The user is not required to add any reagent to the Reader.

The test procedure is very simple, as the user is only required to apply blood to the PAQ and place it into the Cradle. The rest of the test is carried out automatically within 3 minutes. No manipulation of reagents or other materials by the user is required.

Performance Data

The performance validation of the Chempaq XBC Analyzer is divided into: 1) general performance studies; and 2) special studies as described below. Testing was performed under two separate situations: 1) laboratory bench testing; and 2) point-of-use clinical testing, including point-of-care and physician office laboratory locations. Test performance was evaluated for the following parameters:

- Precision and accuracy (general performance);
- Venous vs. capillary samples (general performance);
- Linearity (special study);
- Interferences (special study);
- Pre-analytical errors (special study);
- Stability studies (general performance);
- Batch variability (in-batch and between-batch).

All performance testing was carried out following approved test protocols. Several National Committee for Clinical Laboratory Standards ("NCCLS") and International Council for Standardization in Haematology ("ICSH")

documents were used as reference and are specifically identified in the 510(k) notice. In all instances, the Chempaq XBC Analyzer functioned as intended.

Substantial Equivalence

The Chempaq XBC Analyzer is as safe and effective as the Coulter® A^{C}T™ diff Analyzer. The Chempaq XBC Analyzer has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Chempaq XBC Analyzer and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Chempaq XBC Analyzer is as safe and effective as Coulter® A^{C}T™ diff Analyzer. Thus, the Chempaq XBC Analyzer is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Chempaq A/S
c/o Jonathan S. Kahan
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

DEC 2 2 2005

Re: k050758
Trade/Device Name: Chempaq XBC Analyzer
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: October 28, 2005
Received: October 28, 2005

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K050758

Device Name: Chempaq XBC Analyzer

Indications for Use:

The Chempaq XBC Analyzer is an in vitro diagnostic method intended for the quantitative determination of the concentration of white blood cells ("WBC"); granulocytes ("GRN"); lymphocytes ("LYM"); monocytes ("MON"); and total hemoglobin ("Hb") in whole-blood samples (finger stick or venous sample).

The Chempaq XBC Analyzer is indicated for use in: clinical laboratories, and for point-of-care hematology determinations in doctors' offices or by healthcare professionals in hospital settings to identify and classify one or more of the formed elements of blood.

Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Eval[illegible]y

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